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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

AFREMOVA, VERA

ART UNIT PAPER NUMBER

1651

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/826,393

Applicant(s)

FLORIN ET AL.

Examiner

Vera Afremova

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

Art Unit: 1651

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/25/2003 has been entered.

### ***Status of claims***

Claims 14-33 as amended [8/25/2003] are pending and under examination in the instant office action.

Claims 1-13 were canceled by applicants [Paper No. 6 filed 6/04/2002].

### ***Priority***

Acknowledgment has been made of applicant's claim for foreign priority based on EPO 98118939.4 10/07/1998 during prosecution of the instant application 09/826,393.

However, it is noted that applicants have not filed a certified copy of this document as required by 35 U.S.C. 119(b). The instant application 09/826,393 is a national application not a national stage application under 35 USC 371. The certified copy EPO 98118939.4 has not been provided. The specific reference to the earlier filed foreign application should be made in the instant application in first paragraph of the specification.

### ***Response to Arguments***

Applicants' arguments filed 8/25/2003 have been fully considered but they are not found persuasive for the reasons below.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14, 16, 17, 31 and 32 as amended are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,143,563 [IDS reference A-7] as explained in the prior office action and for the reasons below.

Claims are directed to a process for cryopreservation of primary regeneration tissue wherein the method comprises step of cultivating a plant tissue in an induction medium to induce a primary regeneration tissue comprising embryogenic cells, step of culturing the primary regeneration tissue on a multiplication medium to maintain proliferation and step of cryofreezing the primary regeneration tissue. Some claims are further drawn to additional step of dehydrating the primary regeneration tissue before cryofreezing. Some claims are further drawn to dehydrating in container with over-saturated salt to control relative humidity.

US 6,143,563 teaches a process for cryopreservation of embryogenic callus wherein the method comprises step of cultivating a plant tissue in an induction medium to induce embryogenic callus (col. 8, line 61-65), step of subculturing callus on a multiplication medium (col. 9, lines 3-10), step of dehydrating the callus in a container with over-saturated salt under control of relative humidity (col. 9, lines 12-20) and step of cryofreezing (col. 9, lines 22-25). US 6,143,563 teaches the use of sucrose in the induction medium 605Z (col. 10, line 17) and the use of increased concentration of sucrose in the multiplication medium (col. 9, line 3).

Art Unit: 1651

Thus, the cited patent US 6,143,563 anticipates the claimed method because it comprises identical active steps of culturing, subculturing, dehydrating and cryofreezing and identical structural elements such as the use of embryogenic callus and at least two different media.

The “embryogenic callus” of the cited patent US 6,143,563 is the same plant material as “primary regeneration tissue comprising embryogenic cells” within the meaning of the claims. The “embryogenic callus” of the cited patent US 6,143,563 is not a somatic embryo but it is capable for embryogenesis and for forming somatic embryo. The cited patent provides definitions for embryogenic callus including both types of embryogenic callus (col. 5, lines 9-15) that are suitable for cryopreservation. Although the second type of callus might demonstrate some early somatic embryo morphology, it is not a somatic embryo as taught by the cited patent. Thus, the cited patent teaches cryopreservation of the same plant material as encompassed by the present invention. Moreover, the cited patent teaches that embryogenic callus might be initiated from a variety of plant tissue including embryos (example 3) and plant leaf (col. 5, line 33).

Therefore, applicants’ argument (response page 6, par. 6 and 7), that the cited patent does not teach the same plant material and, thus, the same method, is not found true and/or convincing even considering the applicants’ definitions (response page 5, par. 3 and 4). The cited patent clearly does not teach cryopreservation of a somatic embryo. The cited patent clearly teaches an “embryogenic callus” rather than a generic callus tissue in the method for cryopreservation.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1651

Claims 14, 16-19, 24, 26 and 31-33 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,143,563.

Claims 14, 16, 17, 31 and 32 as explained above. Some claims are/are further drawn to additional pre-freezing step before cryofreezing step wherein temperature is between -20° C and -40° C.

The cited patent US 6,143,563 is relied upon as explained above. In the particular example for cryopreservation of cells of the embryogenic callus the cited patent teaches step of direct plunging of the dehydrated cells into liquid nitrogen (example 3). In generic disclosure the cited patent teaches that the dried cells can be stored or pre-frozen at temperature -20° C before or as alternative to storage in liquid nitrogen (col. 6, lines 26-34). The cited patent also clearly teaches that the slow freezing or pre-freezing of callus cells at temperature -40° C before storage in liquid nitrogen is a classic and common protocol for cryopreservation of callus cells (col. 2, lines 20-23).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to add a pre-freezing or slow cooling step to the method of US 6,143,563 with a reasonable expectation in success in cryopreserving primary regeneration tissue with embryogenic cells or the embryogenic callus because pre-freezing or slow cooling are routine and classic protocols in the methods for cryopreservation of biological materials including callus cells as adequately demonstrated by US 6,143,563. Thus, one of skill in the art would have been motivated to subject the embryogenic callus cells cultures to pre-freezing or slow cooling steps for the expected benefits in successful cryopreservation as recommended by the prior art. Thus, the claimed invention as a whole was clearly prima facie obvious, especially

Art Unit: 1651

in the absence of evidence to the contrary. The claimed subject matter fails to patentably distinguish over the state of the prior art. Therefore, the claims are properly rejected under 35 USC § 103.

Claims 14-33 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,143,563 as applied to claims 14, 16-19, 24, 26 and 31-33 above, and further in view of Pence et al. [Form 892-U], US 5,943,821 [IDS reference B-7] and US 5,922,929 [IDS reference C-7].

Claims 14, 16-19, 24, 26 and 31-33 as explained above. Some claims are further drawn to the use of particular concentrations of sucrose in the induction medium and in the multiplication medium such concentrations 0.4 M and 1 M respectively and to the use of plant material derived from *Theobroma cacao*, *Coffee canephora*, *Coffee arabica* or *Daucus carota* in the method for cryopreservation.

US 6,143,563 is relied upon as explained above for the disclosure of a process for the cryopreservation of an embryogenic callus or primary regeneration tissues comprising embryogenic cells. In the particular example US 6,143,563 teaches the use of sucrose in the induction medium 605Z (col. 10, line 17) and the use of increased concentration of sucrose in the multiplication medium (col. 9, line 3). The cited patent teaches that the use of media with an osmoticum agent such a sucrose improves viability of the cells during freezing process (col. 5, lines 46-50) and that the choice of specie osmoticum and/or its concentration depend on the specific species of plant that are used for induction of embryogenic cells and further cryofreezing (col. 6, lines 49-51). Although the concentration of sucrose in the method of the cited is not

Art Unit: 1651

absolutely the same as presently claimed, the cited patent clearly teaches the increase of sucrose concentration during culturing steps in the method for cryopreservation. Moreover, the cited patent teaches that the choice of osmoticum and, thus, its concentration would depend on the plant species and its determination is within the purview of ordinary skill practitioner.

US 6,143,563 teaches the cryopreservation method that is applicable for the callus cells of a variety of plant species (col. 5, line 25). However, it is silent about induction of callus cells derived from cocoa, coffee or carrot plants or from the plant species of *Theobroma cacao*, *Coffee canephora*, *Coffee arabica* or *Daucus carota*.

However, the cited reference by Pence et al. [U] teaches that plant species such as *Theobroma cacao* is capable to form callus culture (tables 1 and 2, for example). The other references are relied upon to demonstrate that plant species such as *Coffee canephora* is capable to form callus culture (see example 3 of US 5,943,821 [B-7]) that plant species such as *Daucus carota* is capable to form callus culture (see example 1 of US 5,922,929 [C-7]).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice the presently claimed method for cryopreservation of embryogenic callus cells because the protocols for the callus cells induction, culturing and cryopreservation are known in the prior art. The prior art teaches that callus of any plant species can be subjected to cryopreservation and the callus cultures derived from the presently claimed plant species including *Theobroma cacao*, *Coffee canephora* or *Daucus carota* have been demonstrated in the prior art. Thus, one of skill in the art would have been motivated to subject the callus cultures obtained from the plant species of *Theobroma cacao*, *Coffee canephora* or *Daucus carota* to cryopreservation protocols for the benefit of storing the plant materials. The



Art Unit: 1651

use of a particular osmoticum concentration is considered to be within the purview of ordinary skill practitioner as suggested by the cited prior art. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

With regard to the cited references Pence et al. [U], US 5,943,821 [B-7] and US 5,922,929 [C-7] applicants' argument that they do not disclose "primary regeneration tissues comprising embryogenic cells" in the method for cryopreservation (response page 7, par. 3) are not found convincing because the cited references are relied upon to demonstrate that the callus cultures that are "primary regeneration tissues comprising embryogenic cells" have been obtained from the same plant species that are presently claimed. US 6,143,563 teaches that cryopreservation protocols are suitable for a large variety of plant species. The "primary regeneration tissues comprising embryogenic cells" and callus cells including both types of callus cell cultures are the same plant materials within the meaning of the claims and according to the prior art definitions taught by US 6,143,563. Therefore, the claimed method is properly given interpretation under 103 section within the meaning of the subject matter as claimed and as taught by the prior art.

In the instant office action claim rejections over references Hatanaka et al. [IDS-AP], Lecouteux et al. [IDS-AQ], Tessereau et al. [IDS-AR] and Abdelnour-Esquivel et al. [IDS-AO] have been withdrawn because these references teach methods for cryopreservation of plant

Art Unit: 1651

somatic and zygotic embryos but not of the plant callus cells as encompassed by the presently claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351 till January 15, 2004 or (571) 271-0914 after January 15, 2004. The examiner can normally be reached on 9.30 am - 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743 till January 15, 2004 or on (571) 272-0926 after January 15, 2004.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova



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VERA AFREMOVA

December 19, 2003.

PATENT EXAMINER